TAB 3

K092835
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510(K) SUMMARY OF SAFETY & EFFECTIVENESS

FEB 12 2010

Original Date of Submission	14 September 2009
Device Trade Name	ComfortGel Blue Nasal Mask
Common/Usual Name	Ventilator, non-continuous (respirator)
Establishment Registration #	2518422
Address of Mfr. Facility	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-4120
Classification	Class II device
Classification Panel	Anesthesiology Devices
Classification Reference	21 CFR 868.5905
Product Code	BZD – Ventilator, non-continuous (respirator)
Predicate Device(s)	Respironics ComfortGel Full Face Mask (K073600) Respironics Reusable Contour II Nasal Mask (K991648)
Labeling	Draft Labeling can be found in Tab 5.
Intended Use	The ComfortGel Blue Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.
Reason for Submission	Modify the ComfortGel Full Face Mask to provide a nasal mask offering with a gel cushion.

Intended Use

The ComfortGel Blue Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

Device Description

The Respironics ComfortGel Blue Nasal Mask consists of a polycarbonate faceplate with a gel cushion encapsulated in a polyester seal for the face. The mask includes integrated exhalation features on the elbow. It is an accessory for use with CPAP and bi-level devices in the home (single patient use) and hospital/institution (multi-patient use).

The ComfortGel Blue Nasal mask covers the patient's nose only. It is strapped to the patient's face using headgear which connects to the mask via slots in the forehead bracket at the top, and via ball clip headgear attachments, which fit into sockets in the mask faceplate at the bottom. The mask is connected to the CPAP or bi-level flow generator via standard 22mm patient tubing. Positive pressure ventilation is then able to be applied to the lungs in a non-invasive way.

Substantial Equivalence

The ComfortGel Blue Nasal Mask has the following similarities to the previously cleared predicate devices:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

There is no change to the intended use, operating principle, technology or manufacturing process for the ComfortGel Blue nasal mask. Design modifications were made to the previously cleared ComfortGel Full Face Mask (K073600) to provide a nasal mask offering, similar to the Reusable Contour II Nasal Mask, with a gel cushion. The following changes have been made:

1. Modification to the mask materials
2. Removal of pressure pick-off port.
3. Modification to match mask dimensions to that of a nasal mask

4. Modification to the mask elbow to remove entrainment valve, similar to the Reusable Contour II Nasal Mask (K991648).
5. Modification to add additional sizes of the mask.
6. Modification to the mask deadspace.

Table 1 provides a detailed technology and performance comparison for the ComfortGel Blue Nasal Mask to the cited device predicates Reusable Contour II Nasal Mask (K991648) and ComfortGel Full Face Mask (K073600). Differences from the predicate devices are noted by the shaded areas.

Table 1: Device Comparison Table

	Subject Device: **Device:** Respironics ComfortGel Full Face Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K073600	**Predicate Device:** **Device:** Respironics Reusable Contour II Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K991648	**Subject Device:** **Device:** Respironics ComfortGel Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** To be determined
Intended Use	The ComfortGel Full Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for multi-patient use in the home or hospital/institutional environment. The mask is intended to be used on patients (>66 lbs/30kg) for whom CPAP or bi-level therapy has been prescribed using a CPAP or bi-level system.	The Respironics Reusable Contour II Nasal Mask is intended to provide an interface for application of Respironics bi-level or CPAP therapy to patients. For single patient use in the home or hospital/institutional environment. The mask is to be used on adult patients (>30kg) for who bi-level or CPAP therapy has been prescribed using a Respironics bi-level or CPAP system.	The ComfortGel Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is intended to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed using a CPAP or bi-level system.
Patient Population	Patients > 66 lbs/30 kg	Patients >30kg	Unchanged from K073600/K991648
Environment of Use	Home or Hospital/institutional Environment	Home or Hospital/Institutional Environment	Unchanged from K073600/K991648
Product Code	BZD	BZD	Unchanged from K073600/K991648
Provided Sterile or Non-Sterile	Provided clean, not sterile	Provided clean, not sterile	Unchanged from K073600/K991648
Patient Usage Type	Multi-patient Use	Single patient use	Single Patient Use in the home or multi-patient use in the hospital/institutional environment.
Design	Face Interface and headgear	Nasal interface and headgear	Unchanged from K991648
Materials	Faceplate: Polycarbonate Face Seal: gel cushion	Faceplate: Polycarbonate	Faceplate: Polycarbonate Face seal: Gel cushion

	with urethane overlay . Cushion flap: Silicone Exhalation Port: Polycarbonate Entrainment Valve: Polycarbonate with Silicone Flapper Headgear: UBL, Urethane foam and lycra	Face Seal: Silicone Cushion Exhalation Elbow: Polycarbonate Headgear: Velstretch/Lycra laminated foam	with polyester overlay Cushion Flap: Silicone Exhalation Elbow: Polycarbonate Exhalation Port: Delrin Forehead Pad: Silicone Headgear: UBL, Urethane Foam, and Lycra
Number of Pressure Pickoff ports	One	One	None
Shape and size of faceplate	The shape of the faceplate follows the contours of the face allowing clearance of facial features, covering the nose and mouth for therapy. The faceplate attaches to a silicone sealing flap via a retaining ring.	Profile of the faceplate is streamlined for a slightly flatter, rounder and more complete shape to help reduce mask volume.	The shape of the faceplate follows the contours of the face allowing clearance of facial features, covering the nose only for therapy. The faceplate attaches to a silicone sealing flap via a retaining ring.
Shape and size of cushion	Gel cushion to allow for a more comfortable fit and improved mask performance (less leak).	Cushion varies in thickness for better seal and easier fit. The cushion material is thinnest where the cushion contacts the user's nose. Thin cushion material allows three basic mask sizes to fit a broad range of facial features.	Gel cushion to allow for a more comfortable fit and improved mask performance (less leak). Dimensions modified to fit nasal mask.
Safety Valve	The safety valve is integral to the mask.	N/A- nasal mask	Unchanged from K991648
Exhalation device	No accessory exhalation device is required. Exhalation ports are integrated	No accessory exhalation device is required. Exhalation ports are integrated	No accessory exhalation device is required. 54 pin hole exhalation ports are integrated
Anatomical Sites	Nose & mouth	Nose	Unchanged from K991648
Patient Circuit Connection	22 mm entrainment valve elbow	22 mm exhalation elbow	Unchanged from K991648
Pressure Range	4 to 30 cmH2O	4 to 30 cmH2O	Unchanged from K073600/K991648
Number of Mask Sizes	Three – small, medium and large	Three – small, medium and large	Four- petite, small, medium, and large
Mask Deadspace	Small – 210 cc Medium – 260 cc Large – 300 cc	Small: ~95 cc Medium: ~123 cc Large: ~123 cc	Petite: 76 cc Small: 97 cc Medium: 99 cc Large: 118 cc
Intentional Leak	> 9.5 SLPM @ 2.5 cm	≥ 7.5 SLPM @ 1.5 cm H2O	Unchanged from K073600

	H2O > 15 SLPM @ 5 cm H2O < 64 SLPM @ 40 cm H2O	≥ 10 SLPM @ 2.5 cm H2O ≥ 16 SLPM @ 5.0 cm H2O ≤ 67 SLPM @ 40 cm H2O	
Unintentional Leak	≤17 SLPM @20 cm H2O ≤ 28 SLPM @ 35 cm H2O	≤17 SLPM @20 cm H2O ≤ 28 SLPM @ 35 cm H2O	Unchanged from K073600/K991648
Pressure Drop	Closed to Atmosphere: ≤ 1 cm H2O at flows ≤ 50 SLPM ≤ 4 cm H2O at flows ≤ 100 SLPM Open to Atmosphere: ≤ 2 cm H2O @ flow up 60 lpm	Not known	< 1 cmH2O (.98 hPa) at flows ≤ 50 SLPM < 4 cmH2O (3.9 hPa) at flows ≤ 100 SLPM (Elbow without entrainment valve comparable to Elbow with entrainment valve, closed to atmosphere.)
Valve Open to Atmosphere	PAP Pressure ≥ 1cm H2O (0.40 in H2O) and ≤ 3 cm H2O (1.2 in H2O)	N/A- nasal mask	Unchanged from K991648
Valve Close to Atmosphere	PAP Pressure ≥ - 1 cm H2O (-0.40 in H2O)	N/A- nasal mask	Unchanged from K991648
Mask Weight	Small: 5.24 oz. Medium: 5.54 oz. Large: 5.86 oz.	No information available	Petite: ~4.83 oz. Small: ~ 5.39 oz. Medium:~ 5.28 oz. Large: ~ 5.45 oz.
Cushion Height, Length and Width	Small: 4.01" x 3.51" x 1.73" Medium: 4.34" x 3.84" x 1.72" Large: 4.78" x 3.84" x 1.74"	No information available	Petite: 2.26" x 2.45" x 1.47" Small: 2.76" x 2.78" x 1.47" Medium: 2.76" x 2.78" x 1.49" Large: 3.16" x 2.84" x 1.47"
Faceplate Height, Length and Width	Small: 4.82" x 4.00" x 1.09" Medium: 5.03" x 4.32" x	No information available	Petite: 3.25" x 3.25" x 0.97" Small/Medium: 3.62" x

	1.09" Large: 5.47" x 4.32" x 1.09"		3.38" x 0.97" Large: 3.90" x 3.52" x 0.97"
Occluded End Tidal CO2	Small = 7.6% Medium = 6.9% Large = 6.7%	No information available	Large = 7.9%

To demonstrate performance and functionality of the ComfortGel Blue Nasal Mask was unaffected as a result of these changes, extensive performance testing, to include intentional leak, unintentional leak, pressure drop, CO2 rebreathing, deadspace testing and swivel torque was completed on both untreated and treated samples. Testing was performed pre and post home/clinical cleaning and disinfection treatments. Additionally, efficacy testing was performed to ensure that the mask could be high level disinfected to assure a minimum of a 6 log reductions for this mask as tested in accordance with AAMI TIR No. 12-2004, AAMI TIR 30-2003, ANSI/AAMI/ISO 14937-2000, and the "content and format of Premarket notification submissions for liquid chemical sterilants/high level disinfectants" – FDA CDRH, January 3, 2000. Results from this testing concluded that the verification testing raises no new issues of safety or effectiveness.

Respironics has followed the FDA's Guidance for Industry and FDA Staff document "pre-market assessment of pediatric medical devices" and applied the principle of FDA's Least Burdensome Approach to demonstrate the Substantial Equivalence of the ComfortGel Blue Nasal Mask. As a result we conclude that the existing indications for use can be safely and effectively applied to this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 12 2010

Respironics, Incorporated
Ms. Zita A. Yurko
Director, Regulatory Affairs
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K092835
Trade/Device Name: ComfortGel Blue Nasal Mask
Regulation Number: 21CFR 868.5905
Regulation Name: Noncontinuous Ventilator IPPB
Regulatory Class: II
Product Code: BZD
Dated: January 18, 2010
Received: February 2, 2010

Dear Ms. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

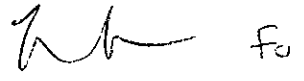
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ComfortGel Blue Nasal Mask

The ComfortGel Blue Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L. Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092835